



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g4471d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-13-04W

VIA FEDERAL EXPRESS

December 18, 2003

Norman Cloutier
Owner
Fairfield Farm Kitchens Inc.
309 Battles Street
Brockton, MA 02401

Dear Mr. Cloutier:

We inspected your seafood processing facility, located at 309 Battles Street, Brockton, MA, on September 24 through 29 and again on October 20, 2003. We found that you have a serious deviation from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6 (g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood products (refrigerated and frozen, cooked, reduced-oxygen-packed, seafood chowders, bases, and bisque products) are adulterated, in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find this Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The serious deviations observed were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the foods safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may

cause a food to be unsafe for human consumption.” However, your firm’s HACCP plan for “seafood fully cooked” does not list the food safety hazard of *Clostridium botulinum* associated with your cooked, reduced-oxygen-packed, seafood chowders, bases, and bisque products covered under this HACCP plan.

We acknowledge your response letter dated October 30, 2003. Your response letter states that you believe that *Clostridium botulinum* is not a hazard because you utilize canned clams which have been previously retorted by your supplier. However, *Clostridium botulinum* is a hazard reasonably likely to occur because once you open the canned seafood products and combine them with other ingredients, such as dairy products and produce, you are potentially re-introducing *Clostridium botulinum* into your final reduced-oxygen-packed seafood product. The ingredients other than the clams are of most concern because they can be a potential source of non-proteolytic *Clostridium botulinum* types B, E, and F. The anerobic conditions present in reduced oxygen and/or modified atmospheric packages, such as yours, are conducive to the growth of *Clostridium botulinum* spores with the potential for toxin formation. Consequently, there must be controls in place to prevent growth and toxin formation from *Clostridium botulinum* in your modified atmospheric products.

If, however, your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled “Important, keep frozen until used, thaw under refrigeration immediately before use,” then formation of *C. botulinum* toxin may not be reasonably likely to occur. A review of your labeling for your reduced oxygen packaged frozen seafood soups revealed they do not adequately provide the thawing instructions on the label to control the food safety hazard of *C. botulinum*. Moreover, during our inspection we found that you were storing and distributing reduced oxygen packaged seafood soups under refrigerated conditions. These products would require additional controls as secondary barriers for the food safety hazard of *C. botulinum*. We recommend that you refer to Chapter 13 in the Fish and Fisheries Products Hazards & Controls Guidance: *Third Edition* for more information on *C. botulinum*.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, your firm’s HACCP plan for “fully cooked seafood” lists a critical limit of “cook product to [REDACTED] greater” at the “cook stage” critical control point that is not adequate to control the food safety hazard of pathogen survival. An adequate cook critical limit should specify time and temperature parameters. We recommend that you refer to Chapter 16 in the Fish and

Fisheries Products Hazards & Controls Guidance: *Third Edition* for more information on cooking critical limits.

We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response any documentation, such as your HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

for 
Gail T. Costello
District Director
New England District Office

cc: Frank Carpenito
President / CEO
Fairfield Farm Kitchens Inc.
309 Battles Street
Brockton, MA 02401